

## Vaccine Briefs

**Pediarix:** Our first Vaccine Brief concerns Pediarix, a new pediatric combination vaccine. Pediarix was licensed by the US Food and Drug Administration in December 2002. Pediarix contains DTaP, hepatitis B, and inactivated polio vaccines. The DTaP component is Infanrix, and the hepatitis B component is Engerix-B. Pediarix is approved for the first three doses of the DTaP and IPV series, which are usually given at about 2, 4, and 6 months of age. However, Pediarix is approved for use through 6 years of age, the same as the DTaP component. This means that a child who is behind schedule can still receive Pediarix as long as it is given for doses one, two, or three of the series, and the child is younger than 7 years of age.

One of the most common questions we receive about Pediarix is its use for the fourth and fifth doses of the DTaP series. Pediarix is not approved by FDA for these doses of the DTaP series. However, the childhood immunization schedule includes a statement about the use of combination vaccines which can cause some confusion. The rule says that **combination vaccines may be used whenever any components of the combination are indicated and the vaccine's other components are not contraindicated**. This statement has been interpreted by some providers as allowing off-label use of Pediarix for the fourth and fifth doses of the series.

We have discussed this issue internally at the National Immunization Program, and presented it to the Advisory Committee on Immunization Practices at their June 2004 meeting. ACIP referred the issue to the groups working on the harmonized schedule and the revision of the General Recommendations, so we do not have input from them yet. The National Immunization Program's opinion is that Pediarix should be used only for the doses for which it has been approved by FDA. Since FDA has not approved Pediarix for the fourth and fifth doses, we recommend you **not use it for these doses**, regardless of the combination vaccine statement on the schedule. A possible **exception to this would be if a child is eligible for the fourth or fifth dose and Pediarix is the only DTaP vaccine available** to you. In this case it is probably preferable to use Pediarix off-label than to allow the child to leave the office without the DTaP dose.

We have received numerous inquiries about doses of Pediarix inadvertently administered as booster doses. For instance, if Pediarix administered as a child's fourth or fifth dose of DTaP can be counted as a valid dose. I will repeat here that FDA has not approved Pediarix for booster doses, so you should not use it in this situation. However, if Pediarix has been inadvertently administered as the fourth or fifth dose of DTaP or the fourth dose of IPV, it is not necessary to repeat the dose.

**National Immunization Survey:** The National Immunization Survey provides estimates of vaccination coverage among children aged 19 through 35 months for each of the 50 states and 28 selected urban areas. First conducted in 1994 as part of the Childhood Immunization Initiative, NIS is a quarterly random digit dialing sample of telephone numbers for each of the 78 survey areas. The calendar year 2003 results reflected a sample of more than 21,000 children, and were released on July 29, 2004. This is what Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention, had to say about the results.

Let me end with a hopeful perspective. This is the record year for immunization coverage in the United States. This is the record year for protecting our children from vaccine preventable diseases but we have challenges and we need your help and we need everyone to commit to protecting every child from these sometimes devastating illnesses. Thank you.

The 2003 NIS data were published in Morbidity and Mortality Weekly Report on July 30, 2004. There is a link to the report on our broadcast resources website. The 2003 results indicate that childhood immunization levels are at record high levels.

This table shows selected results from the 2003 data. Coverage for **DTaP 4**, the most difficult dose to get in, increased by an impressive 3% since 2002. Coverage for 3 doses of **hepatitis B** vaccine increased 2%, and is above 90% for the first time. This is the first full year that **pneumococcal conjugate vaccine** has been included in NIS. Even with intermittent shortages, two thirds of children had receive at least 3 doses. **Varicella** coverage increased 4% to 85%, the highest ever measured. Finally, the coverage levels for the various **combined series** increased 4% to 5%, reflecting increases in the individual antigens. This is really great news. And we know that these record high coverage levels are the result of hard work by all of you out there on the front lines. The National Immunization Program greatly appreciates all your efforts. I think you should all give yourselves a round of applause.

Despite the good news, the job is not done. There is substantial variation in coverage levels between states, and between states and urban areas. We still have a ways to go to reach the 2010 national objective of 90% for the combined vaccination series. And of course, 11,000 more children are born every day, all with a vaccination level of zero. So celebrate your successes today. Tomorrow, renew your efforts to ensure that no child, adolescent or adult will have to needlessly suffer from a vaccine preventable disease.

**Vaccine Information Statements:** Risk and benefit communication between the provider and the person receiving the vaccine is essential. The cornerstone of immunization patient education is the Vaccine Information Statement, or VIS. **Every healthcare provider, public or private, who administers a vaccine covered by the National Childhood Vaccine Injury Act is required by law to**

**provide a copy of the most current VIS with each dose of vaccine administered.** Not only the first dose, but every dose. In addition, CDC encourages healthcare providers to use all available VISs, whether the National Childhood Vaccine Injury Act covers the vaccine or not. It is just good practice. Healthcare providers should also encourage the patient or their representative to take the VIS home. This is important because the VIS contains information that may be needed later, including the recommended schedule for that vaccine, information concerning what to look for and do after the vaccination, and what to do if there is a serious reaction.

Healthcare providers are **not required by Federal law to obtain the signature** of the patient or their representative acknowledging receipt of the VIS. The VISs are not designed as informed consent documents. But while the federal government does not require informed consent for vaccinations, some states do. You should consult your agency or state immunization program to determine if there are any specific informed consent requirements. Documentation that the VIS was given is required. Healthcare providers **must note in each patient's permanent medical record or in a permanent office log or file, the date printed on the VIS and the date the VIS is given to the vaccine recipient, or their legal representative.** Every VIS is dated. The date is always located in the corner of the second page of the document, and sometimes on the first page as well. This is the date that must be recorded in the patient's chart. VISs change periodically. Paying attention to this date also helps to ensure that your office always has the most current version of each VIS. Speaking of most current versions, this table lists Vaccine Information Statements that are new or revised since our last Immunization Update broadcast in August 2003. There are **new statements for rabies and typhoid** vaccines, for those of you who vaccinate travelers or persons with occupational risk of rabies. VISs for **inactivated influenza vaccine, live attenuated influenza vaccine, and hepatitis A** vaccine have been revised. The **MMR** VIS was modified slightly for clarity. The edition date did not change. Information about the Vaccine Adverse Event Reporting System – **VAERS- was clarified on all statements.** As a general rule, it is not necessary to throw out your old statements unless a major change has been made. Just replace your supply with the new version when you run out of the older version.

All English language Vaccine Information Statements are available from the National Immunization Program and state immunization programs. VISs are available in more than 25 languages on the Immunization Action Coalition website. We will have a link to all the Vaccine Information Statements on our broadcast resources website.

**Global Polio Eradication:** For our last vaccine brief, we would like to update you on the status of global polio eradication. The Global Polio Eradication Initiative was launched by the World Health Assembly in 1988. At that time 125 countries were considered endemic for wild poliovirus. The World Health Organization, CDC, Rotary International, and UNICEF are the principal partners. National governments, private foundations, nongovernmental organizations, corporations,

and volunteers are all collaborating to achieve eradication. In 2003, a total of 784 cases of polio were reported from 6 countries. These countries, shown on this map in red are located in 3 WHO regions – Africa, Eastern Mediterranean, and South East Asia. Almost 75% of all cases in 2003 occurred in just two countries, Nigeria and India. In the first half of 2004, Nigeria accounted for 78% of cases reported globally.

Three endemic countries – Egypt, India, and Pakistan, recorded their lowest ever levels of transmission during the second half of 2003. Unfortunately, 51 imported cases were reported by 10 countries previously considered polio free. This is the first time that the number of countries reporting importations was larger than the number of endemic countries. Eight of these countries are in west and central Africa.

The largest increase in cases occurred in Nigeria. In August 2003, several northern Nigerian states suspended polio vaccination programs because of rumors that the vaccine had been adulterated with HIV and infertility agents. Fortunately, the ban on OPV was recently lifted and vaccination programs began again in July.

Several challenges to global eradication remain. These include: **maintaining high-quality surveillance and immunization activities; gaining access to children in conflict affected countries; providing sufficient oral polio vaccine; and ensuring political and financial support** until certification of global eradication can be achieved.

You may be able to help meet at least one of these challenges. CDC continues to recruit healthcare professionals for short-term field assignments to polio endemic countries. This program is called Stop Transmission of Polio, or STOP. During a 3 month assignment team members may **conduct and evaluate active surveillance; assist with case investigations and follow-up** as well as conduct measles outbreak investigations; help to **plan, implement and evaluate supplemental immunization activities** such as national immunization days; and **develop and strengthen data management systems for the national immunization programs**. A STOP team assignment is not for everyone. But it can be a very rewarding experience. We will provide a link to information about the STOP program on our broadcast resources website.